

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC.,)	
PAR STERILE PRODUCTS, LLC, and)	
ENDO PAR INNOVATION)	
COMPANY, LLC,)	
)	
Plaintiffs,)	C.A. No. 18-823-CFC
)	
v.)	
)	
EAGLE PHARMACEUTICALS INC.,)	
)	
Defendant.)	

JOINT CLAIM CONSTRUCTION CHART

Pursuant to Paragraph 8 of the Court’s Scheduling Order (D.I. 20), Plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, “Plaintiffs”) and Defendant Eagle Pharmaceuticals Inc. (“Eagle”) hereby submit this Joint Claim Construction Chart identifying for the Court the claim terms of U.S. Patent Nos. 9,375,478 (the “’478 patent”), 9,744,239 (the “’239 patent”), 9,687,526 (the “’526 patent”), 9,750,785 (the “’785 patent”), 9,744,209 (the “’209 patent”), and 9,937,223 (the “’223 patent”) for which the parties have a dispute, together

with the parties' proposed constructions of the disputed claim language¹ and citations to the supporting intrinsic evidence.

The parties have agreed that the claim term "vasopressin" should be construed as "Arginine vasopressin as described in SEQ. ID. NO. 1 (*see, e.g.*, '239 patent, cols. 25-26)" with respect to each of the '478, '526, '209, '239, '785, and '223 patents.

¹ Eagle's Position: Given the parties' material disputes over the scope of the claim terms at issue, Eagle objects to Par's adoption of "ordinary meaning" for all disputed claim terms, without setting forth what it contends are those ordinary meanings. *See, e.g., NobelBiz, Inc. v. Global Connect, L.L.C.*, 701 F. App'x 994, 997 (Fed. Cir. 2017) ("'[P]lain and ordinary' meaning may be inadequate . . . when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." (citation omitted)); 1 Robert A. Matthews, Jr., Annotated Patent Digest § 4:5 (2019) ("[W]hen a discovery order, a case management order, or a local rule requires a party to provide its contentions relating to claim constructions[,] it is generally improper for a party to state generally that the ordinary meanings of the claim terms should govern and then refuse to set forth what it contends are those ordinary meanings.") (collecting cases); Hon. Leonard P. Stark, Revised Procedures for Managing Patent Cases 8 (2014) ("[The Court is] usually not persuaded that 'plain and ordinary meaning' is an appropriate resolution of a material dispute over the scope of a claim term."). Eagle will object to any attempt by Par to present untimely constructions for the disputed terms through claim construction briefing, expert discovery or otherwise.

Par's Response: It is well-established that Par's proposed ordinary meaning constructions are entirely proper, and that courts do not err by construing claim terms to have their ordinary meaning, without providing a specific construction thereof. *See, e.g., Mentor H/S, Inc. v. Medical Device Alliance, Inc.*, 244 F.3d 1365, 1380 (Fed. Cir. 2001); *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015); *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1326 (Fed. Cir. 2012). In several instances, the ordinary meaning of terms Eagle has identified for construction is readily understandable, and the limitations need no further construction. The nature of the parties' disputes with respect to each such limitation is readily apparent from Eagle's proposed constructions. Those disputes will be fleshed out and the parties' respective positions defended during claim construction briefing.

DATED: March 4, 2019

Respectfully submitted,

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<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"vasopressin degradation products"	'239	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'239 Patent (Exhibit 1)</u> 2:33-3:38 (including Table 1); 5:58-64; 16:6-19:45 (including Example 1, Table 3, and Figs. 5-6)</p> <p><u>'239 File History</u> August 14, 2015 Office Action Response (PAR-VASO-0007062-7073, at 7069-70) (Exhibit 7)</p> <p>August 11, 2015 Vandse Declaration including Appendices A-R (PAR-VASO-0007074-7128) (Exhibit 8)</p>	<p><u>Proposed Construction:</u> "The compounds listed in TABLE 1, having SEQ ID NOs. 2–17"</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'239 Patent (Exhibit 1)</u> 3:1–39, 16:5–20:5, Claims 1–4, Figs. 3–6</p> <p><u>'239 File History</u> Kannan Decl. (Appl. No. 14/717,877 ('239 Patent)) (May. 22, 2017) (Exhibit 11)</p> <p>Office Action Response (Appl. No. 14/717,877 ('239 Patent)) (May. 22, 2017) (Exhibit 12)</p> <p>Vandse Decl. (Appl. No. 14/717,877 ('239 Patent)) (Aug. 11, 2015) (Exhibit 8)</p> <p>Office Action Response (Appl. No. 14/717,877 ('239 Patent)) (Aug. 14, 2015) (Exhibit 7)</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"administering to the human a unit dosage form"	'478, '209	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'478 Patent (Exhibit 2)</u> 1:29-41; 5:45-47; 7:28-51; 8:23-27; 21:29-32, 21:37-49; 22:3-5; 23:20-24</p> <p><u>'209 Patent (Exhibit 4)</u> 1:44-59; 6:23-26; 11:48-12:5; 12:45-46; 45:65-46:3; 60:21-23; 60:31-44; 60:65-67; 62:14-18; 101 (Table 47); 102 (Table 50)</p> <p><u>'526 Patent (Exhibit 3)</u> Claim 16</p> <p><u>'239 File History</u> Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) all pages (Sep. 9, 2016) – PAR-VASO-0008681-8686 (Exhibit 9)</p>	<p><u>Proposed Construction:</u> "Administering to the human a unit dosage form having the properties recited in the claim (does not permit dilution before administration)."</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'478 Patent (Exhibit 2)</u> 1:29-32, 5:45-51, 8:34-9:24, 21:20-51, 23:20-42, 24:30-62, Claim 1</p> <p><u>'209 Patent (Exhibit 4)</u> 1:44-47, 6:26-30, 12:45-46, 13:35-47:20, 60:21-67, Claim 1</p> <p><u>'239 Patent (Exhibit 1)</u> Claim 1, Claim 15</p> <p><u>'239 File History</u> Response to Office Non-Final Action (Appl. No. 14/717,877 ('239 Patent)) 7 (May 22, 2017) (Exhibit 12)</p> <p>Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 7-8 (Nov. 3, 2016) (Exhibit 10)</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
		Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 1-2, 4-5 (Nov. 3, 2016) – PAR-VASO-008701-8705 (Exhibit 10)	Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) 1 (Sep. 9, 2016) (Exhibit 9)
“administering the diluted unit dosage form to the human by intravenous administration”	'239	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'239 Patent (Exhibit 1)</u> 1:30-46; 5:58-60; 7:45-8:2; 8:41-46; 22:24-26; 22:31-44; 22:64-67; 24:15-19</p> <p><u>'526 Patent (Exhibit 3)</u> Claim 16</p> <p><u>'239 File History</u> Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) all pages (Sep. 9, 2016) – PAR-VASO-0008681-8686 (Exhibit 9)</p> <p>Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 1-2, 4-5</p>	<p><u>Proposed Construction:</u> “Administering the diluted unit dosage form generated by diluting the unit dosage form having the properties recited in the claim to the human by intravenous administration.”</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'239 Patent (Exhibit 1)</u> 1:32–35, 5:58–64, 8:52–9:61, 22:20–45, 22:64–67, Claim 1, Claim 15</p> <p><u>'239 File History</u> Response to Office Non-Final Action (Appl. No. 14/717,877 ('239 Patent)) 7 (May 22, 2017) (Exhibit 12)</p> <p>Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 7–8 (Nov. 3, 2016) (Exhibit 10)</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
		(Nov. 3, 2016) – PAR-VASO-008701-8705 (Exhibit 10)	Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) 1 (Sep. 9, 2016) (Exhibit 9)
“intravenously administering the pharmaceutical composition to the human”	'526	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'526 Patent (Exhibit 3)</u> 1:40-57; 7:6-8; 11:47-12:4; 12:44-45; 45:60-64; 59:59-61; 60:3-16; 60:37-39; 61:54-58; 100 (Table 47); 101 (Table 50); Claim 16</p> <p><u>'239 File History</u> Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) all pages (Sep. 9, 2016) – PAR-VASO-0008681-8686 (Exhibit 9)</p> <p>Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 1-2, 4-5</p>	<p><u>Proposed Construction:</u> “Intravenously administering the pharmaceutical composition to the human having the properties recited in the claim (does not permit dilution before administration).”</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'526 Patent (Exhibit 3)</u> 1:41–45, 11:50–59, 13:28–47:15, 59:20–60:39, Claim 1</p> <p><u>'239 Patent (Exhibit 1)</u> Claim 1, Claim 15</p> <p><u>'239 File History</u> Response to Office Non-Final Action (Appl. No. 14/717,877 ('239 Patent)) 7 (May 22, 2017) (Exhibit 12)</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"intravenously administering the pharmaceutical composition to the human" (continued)	'526	(Nov. 3, 2016) – PAR-VASO-008701-8705 (Exhibit 10)	Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 7–8 (Nov. 3, 2016) (Exhibit 10) Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) 1 (Sep. 9, 2016) (Exhibit 9)
"intravenously administering the portion of the pharmaceutical composition to the human"	'223	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'223 Patent (Exhibit 6)</u> 1:38- 54; 7:24-26; 12:48-13:5; 13:45-46; 46:65-47:3; 50:13-37; 55:30-56:28; 62:38-40; 62:48-61; 63:16-18; 64:40-44; 103 (Table 47); 104 (Table 50)</p> <p><u>'526 Patent (Exhibit 3)</u> Claim 16</p> <p><u>'239 File History</u> Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) all</p>	<p><u>Proposed Construction:</u> "Intravenously administering the portion of the pharmaceutical composition to the human having the properties recited in the claim (does not permit dilution before administration)."</p> <p><u>Supporting Intrinsic Evidence:</u> <u>'223 Patent (Exhibit 6)</u> 1:40–43, 7:24–30, 13:45–46, 14:35–48:20, 62:30–62, 63:16–18, 125:31–47, Claim 1</p> <p><u>'239 Patent (Exhibit 1)</u> Claim 1, Claim 15</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
“intravenously administering the portion of the pharmaceutical composition to the human” (continued)	'223	pages (Sep. 9, 2016) – PAR-VASO-0008681-8686 (Exhibit 9) Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 1-2, 4-5 (Nov. 3, 2016) – PAR-VASO-008701-8705 (Exhibit 10)	<u>'239 File History</u> Response to Office Non-Final Action (Appl. No. 14/717,877 ('239 Patent)) 7 (May 22, 2017) (Exhibit 12) Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 7–8 (Nov. 3, 2016) (Exhibit 10) Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) 1 (Sep. 9, 2016) (Exhibit 9)
“intravenously administering the second portion of the pharmaceutical composition to the human”	'223	<u>Proposed Construction:</u> Ordinary meaning, no construction necessary <u>Supporting Intrinsic Evidence:</u> <u>'223 Patent (Exhibit 6)</u> 1:38- 54; 7:24-26; 12:48-13:5; 13:45-46; 46:65-47:3; 50:13-37; 55:30-56:28; 62:38-40; 62:48-61; 63:16-18; 64:40-44; 103 (Table 47); 104 (Table 50)	<u>Proposed Construction:</u> “Intravenously administering the second portion of the pharmaceutical composition to the human having the properties recited in the claim (does not permit dilution before administration).” <u>Supporting Intrinsic Evidence:</u> <u>'223 Patent (Exhibit 6)</u> 1:40–43, 7:24–30, 13:45–46, 14:35–48:20, 62:30–62, 63:16–18, 125:31–47, Claim 1

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
“intravenously administering the second portion of the pharmaceutical composition to the human” (continued)	'223	<p><u>'526 Patent (Exhibit 3)</u> Claim 16</p> <p><u>'239 File History</u> Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) all pages (Sep. 9, 2016) – PAR-VASO-0008681-8686 (Exhibit 9)</p> <p>Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 1-2, 4-5 (Nov. 3, 2016) – PAR-VASO-008701-8705 (Exhibit 10)</p>	<p><u>'239 Patent (Exhibit 1)</u> Claim 1, Claim 15</p> <p><u>'239 File History</u> Response to Office Non-Final Action (Appl. No. 14/717,877 ('239 Patent)) 7 (May 22, 2017) (Exhibit 12)</p> <p>Response to Final Office Action (Appl. No. 14/717,877 ('239 Patent)) 7–8 (Nov. 3, 2016) (Exhibit 10)</p> <p>Applicant-Initiated Interview Summary (Appl. No. 14/717,877 ('239 Patent)) 1 (Sep. 9, 2016) (Exhibit 9)</p>
“acetate buffer”	'223	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p> <p><u>Supporting Intrinsic Evidence:</u></p>	<p><u>Proposed Construction:</u> “A solution containing a mixture of acetic acid and acetate that is capable of resisting changes in pH upon the addition of acidic or basic substances (acetic acid for pH adjustment is not an acetate buffer).”</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"acetate buffer" (continued)	'223	<u>'223 Patent (Exhibit 6)</u> 50:57-65; 61:7-17; Example 12 (col. 102); Table 48 (cols. 103-104); Table 51 (col. 104); Table 56 (cols. 107-108); 128:11-14	<u>Supporting Intrinsic Evidence:</u> <u>'223 Patent (Exhibit 6)</u> 14:35–46:64, 50:57–65, 51:29–41, 55:30– 67, 61:54–57, 62:15–27, 99:45–50, 102:6– 14, 103:1–104:67, 108:45–67, 128:11–14 <u>'026 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,338 ('026 Patent)) 6 (Dec. 7, 2017) (Exhibit 14) <u>'006 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,305 ('006 Patent)) 6–7 (Jan. 26, 2018) (Exhibit 15) <u>'827 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,322 ('827 Patent)) 6–7 (Jan. 26, 2018) (Exhibit 17) <u>'234 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,330 ('234 Patent)) 6–7 (Nov. 27, 2017) (Exhibit 19)

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"acetate buffer" (continued)	'223		<p><u>'520 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,334 ('520 Patent)) 6 (Jan. 26, 2018) (Exhibit 16)</p> <p><u>'649 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,336 ('649 Patent)) 6 (Jan. 26, 2018) (Exhibit 18)</p> <p><u>'223 File History</u> C. Mohan, Buffers: A Guide for the Preparation & Use of Buffers in Biological Systems 19 (2006) (cited in Information Disclosure Statement (Appl. No. 15/612,649 ('223 Patent)) 2 (Dec. 7, 2017)) (Exhibit 13)</p> <p><u>'239 File History</u> Kannan Decl. (Appl. No. 14/717,877 ('239 Patent)) ¶¶ 19–20 (May 22, 2017) (Exhibit 11)</p>
"10 mM acetate buffer"	'478	<p><u>Proposed Construction:</u> Ordinary meaning, no construction necessary</p>	<p><u>Proposed Construction:</u> "A solution containing a mixture of acetic acid and acetate, with a total</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"10 mM acetate buffer" (continued)	'478	<p><u>Supporting Intrinsic Evidence:</u></p> <p><u>'478 Patent (Exhibit 2)</u> 11:21-29; 19:58-67; 20:49-51</p>	<p>concentration of 10 mM, that is capable of resisting changes in pH upon the addition of acidic or basic substances (acetic acid for pH adjustment is not an acetate buffer)."</p> <p><u>Supporting Intrinsic Evidence:</u></p> <p><u>'478 Patent (Exhibit 2)</u> 11:21-29, 11:59-12:3, 20:49-52, 21:5-20, 23:20-26</p> <p><u>'026 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,338 ('026 Patent)) 6 (Dec. 7, 2017) (Exhibit 14)</p> <p><u>'006 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,305 ('006 Patent)) 6-7 (Jan. 26, 2018) (Exhibit 15)</p> <p><u>'827 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,322 ('827 Patent)) 6-7 (Jan. 26, 2018) (Exhibit 17)</p>

<u>Claim Term or Element</u>	<u>Patent</u>	<u>Par's Proposed Construction and Supporting Intrinsic Evidence</u>	<u>Eagle's Proposed Construction and Supporting Intrinsic Evidence</u>
"10 mM acetate buffer" (continued)	'478		<p><u>'234 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,330 ('234 Patent)) 6–7 (Nov. 27, 2017) (Exhibit 19)</p> <p><u>'520 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,334 ('520 Patent)) 6 (Jan. 26, 2018) (Exhibit 16)</p> <p><u>'649 File History</u> Response to Non-Final Office Action (Appl. No. 15/688,336 ('649 Patent)) 6 (Jan. 26, 2018) (Exhibit 18)</p> <p><u>'223 File History</u> C. Mohan, Buffers: A Guide for the Preparation & Use of Buffers in Biological Systems 19 (2006) (cited in Information Disclosure Statement (Appl. No. 15/612,649 ('223 Patent)) 2 (Dec. 7, 2017)) (Exhibit 13)</p>

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			<u>'239 File History</u> Kannan Decl. (Appl. No. 14/717,877 ('239 Patent)) ¶¶ 19–20 (May 22, 2017) (Exhibit 11)